

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

*AMENDMENTS TO THE CLAIMS*

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical composition agent into a human, and wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition and wherein the pharmaceutical agent is selected from the group consisting of paclitaxel, docetaxel, taxanes, camptothecin, propofol, amiodarone, cyclosporine, rapamycin, amphotericin, liothyronine, epothilones, colchicines, thyroid hormones, vasoactive intestinal peptide, corticosteroids, melatonin, tacrolimus, mycophenolic acids.

2. (Cancelled).

3. (Cancelled).

4. (Currently Amended) The pharmaceutical composition of claim ~~[[3]]~~ 1, wherein the pharmaceutical agent is propofol.

5. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is a liquid and comprises from about 0.1% to about 25% by weight of albumin.<sup>1</sup>

6. (Original) The pharmaceutical composition of claim 5, wherein the pharmaceutical composition comprises about 0.5% to about 5% by weight of albumin.

7. (Currently Amended) The pharmaceutical composition of claim ~~[[5]]~~ 1, wherein the pharmaceutical composition is dehydrated.

<sup>1</sup> The claim as filed recites "about 25%." The term "about" was inadvertently omitted in the claim listings in Response to Office Actions.

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

8. (Original) The pharmaceutical composition of claim 6, wherein the pharmaceutical composition is lyophilized.

9. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a mesylate salt of deferoxamine.

10. (Original) The pharmaceutical composition of claim 9, wherein the pharmaceutical composition is a liquid and comprises from about 0.0001% to about 0.5% by weight of deferoxamine mesylate.

11. (Original) The pharmaceutical composition of claim 10, wherein the pharmaceutical composition comprises about 0.1% by weight of deferoxamine mesylate.

12. (Currently Amended) The pharmaceutical composition of claim [[10]] 9, wherein the pharmaceutical composition is dehydrated.

13. (Original) The pharmaceutical composition of claim 12, wherein the pharmaceutical composition is lyophilized.

14. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is an oil-in-water emulsion.

15. (Original) The pharmaceutical composition of claim 5, wherein the pharmaceutical agent is propofol.

16. (Original) The pharmaceutical composition of claim 10, wherein the pharmaceutical agent is propofol.

17. (Original) The pharmaceutical composition of claim 9, wherein the pharmaceutical agent is propofol, the propofol is present in an amount from about 0.1% to about 5% by weight, the albumin is present in an amount from about 0.1% to about 25% by weight, and the deferoxamine mesylate is present in an amount from about 0.0001% to about 0.5% by weight.

Page 3 of 14

pa-1046029 v4

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

18. (Currently Amended) A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical composition agent into a human, and wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit oxidation in the pharmaceutical composition and wherein the weight ratio of albumin to pharmaceutical agent is about 18:1 or less.

19-83. (Cancelled)

84. (Currently amended). The A pharmaceutical composition of claim 1, comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical agent into a human, wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition, and wherein the weight ratio of albumin to pharmaceutical agent is about 18:1 or less.

85-96. (Cancelled).

97. (New) The pharmaceutical composition of claim 1, wherein the albumin and the pharmaceutical agent in the composition are formulated as nanoparticles.

98. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is free of Cremophor.

99. (New) The pharmaceutical composition of claim 1, wherein the albumin is human serum albumin.

100. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical agent is a taxane.

101. (New) The pharmaceutical composition of claim 100, wherein the taxane is paclitaxel.

Page 4 of 14

pa-1046029 v4

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

102. (New) The pharmaceutical composition of claim 100, wherein the taxane is docetaxel.

103. (New) A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical agent into a human, wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition, wherein the pharmaceutical composition comprises about 1% to about 25% by weight of albumin, and wherein the pharmaceutical composition is dehydrated.

104. (New) The pharmaceutical composition of claim 116, wherein the pharmaceutical composition is lyophilized.

105. (New) A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical agent into a human, wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition, wherein the pharmaceutical composition comprises about 0.0001% to about 0.5% by weight of deferoxamine mesylate, and wherein the pharmaceutical composition is dehydrated.

106. (New) The pharmaceutical composition of claim 118, wherein the pharmaceutical composition is lyophilized.

107. (New) A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical agent into a human, wherein the pharmaceutically acceptable carrier comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition, and wherein the pharmaceutical composition is oil-in-water emulsion.

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

108. (New) The pharmaceutical composition of claim 18, wherein the weight ratio of albumin to pharmaceutical agent is about 15:1 or less.

109. (New) The pharmaceutical composition of claim 108, wherein the weight ratio of albumin to pharmaceutical agent is about 9:1 or less.

110. (New) The pharmaceutical composition of claim 109, wherein the weight ratio of albumin to pharmaceutical agent is from about 1:1 to about 9:1.

111. (New) The pharmaceutical composition of claim 18, wherein the albumin and the pharmaceutical agent in the composition are formulated as nanoparticles.

112. (New) The pharmaceutical composition of claim 18, wherein the pharmaceutical composition is free of Cremophor.

113. (New) The pharmaceutical composition of claim 18, wherein the albumin is human serum albumin.

114. (New) The pharmaceutical composition of claim 18, wherein the pharmaceutical agent is selected from the group consisting of paclitaxel, docetaxel, taxanes, camptothecin, propofol, amiodarone, cyclosporine, rapamycin, amphotericin, liothyronine, epothilones, colchicines, thyroid hormones, vasoactive intestinal peptide, corticosteroids, melatonin, tacrolimus, mycophenolic acids.

115. (New) The pharmaceutical composition of claim 114, wherein the pharmaceutical agent is a taxane.

116. (New) The pharmaceutical composition of claim 115, wherein the taxane is paclitaxel.

117. (New) The pharmaceutical composition of claim 116, wherein the weight ratio of albumin to paclitaxel is about 15:1 or less.

Page 6 of 14

pa-1046029 v4

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

118. (New) The pharmaceutical composition of claim 117, wherein the weight ratio of albumin to paclitaxel is about 9:1 or less.

119. (New) The pharmaceutical composition of claim 118, wherein the weight ratio of albumin to paclitaxel is about 1:1 to about 9:1.

120. (New) The pharmaceutical composition of claim 116, wherein the albumin and the paclitaxel in the composition are formulated as nanoparticles.

121. (New) The pharmaceutical composition of claim 116, wherein the pharmaceutical composition is free of Cremophor.

122. (New) The pharmaceutical composition of claim 116, wherein the albumin is human serum albumin.

123. (New) The pharmaceutical composition of claim 115, wherein the taxane is docetaxel.

124. (New) The pharmaceutical composition of claim 123, wherein the weight ratio of albumin to docetaxel is about 15:1 or less.

125. (New) The pharmaceutical composition of claim 123, wherein the albumin is human serum albumin.

126. (New) The pharmaceutical composition of claim 123, wherein the albumin and the docetaxel in the composition are formulated as nanoparticles.

127. (New) The pharmaceutical composition of claim 123, wherein the pharmaceutical composition is free of Cremophor.

128. (New) The pharmaceutical composition of claim 84, wherein the weight ratio of albumin to pharmaceutical agent is about 15:1 or less.

Page 7 of 14

pa-1046029 v4

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

129. (New) The pharmaceutical composition of claim 128, wherein the weight ratio of albumin to pharmaceutical agent is about 9:1 or less.

130. (New) The pharmaceutical composition of claim 129 wherein the weight ratio of albumin to pharmaceutical agent is from about 1:1 to about 9:1.

131. (New) The pharmaceutical composition of claim 84, wherein the albumin and the pharmaceutical agent in the composition are formulated as nanoparticles.

132. (New) The pharmaceutical composition of claim 84, wherein the pharmaceutical composition is free of Cremophor.

133. (New) The pharmaceutical composition of claim 84, wherein the albumin is human serum albumin.

134. (New) The pharmaceutical composition of claim 84, wherein the pharmaceutical agent is selected from the group consisting of paclitaxel, docetaxel, taxanes, camptothecin, propofol, amiodarone, cyclosporine, rapamycin, amphotericin, liothyronine, epothilones, colchicines, thyroid hormones, vasoactive intestinal peptide, corticosteroids, melatonin, tacrolimus, mycophenolic acids.

135. (New) The pharmaceutical composition of claim 134, wherein the pharmaceutical agent is a taxane.

136. (New) The pharmaceutical composition of claim 135, wherein the taxane is paclitaxel.

137. (New) The pharmaceutical composition of claim 136, wherein the weight ratio of albumin to paclitaxel is about 15:1 or less.

138. (New) The pharmaceutical composition of claim 137, wherein the weight ratio of albumin to paclitaxel is about 9:1 or less.

Application No. 10/731,224 (LVM 225602)

Reply to Office Action

139. (New) The pharmaceutical composition of claim 138, wherein the weight ratio of albumin to paclitaxel is about 1:1 to about 9:1.

140. (New) The pharmaceutical composition of claim 136, wherein the albumin and the paclitaxel in the composition are formulated as nanoparticles.

141. (New) The pharmaceutical composition of claim 136, wherein the pharmaceutical composition is free of Cremophor.

142. (New) The pharmaceutical composition of claim 136, wherein the albumin is human serum albumin.

143. (New) The pharmaceutical composition of claim 135, wherein the taxane is docetaxel.

144. (New) The pharmaceutical composition of claim 143, wherein the weight ratio of albumin to docetaxel is about 15:1 or less.

145. (New) The pharmaceutical composition of claim 143, wherein the albumin and the docetaxel in the composition are formulated as nanoparticles.

146. (New) The pharmaceutical composition of claim 143, wherein the pharmaceutical composition is free of Cremophor.

147. (New) The pharmaceutical composition of claim 143, wherein the albumin is human serum albumin.

148. (New) The pharmaceutical composition of claim 97, wherein the nanoparticles have a mean size of less than about 200 nm.

149. (New) The pharmaceutical composition of claim 111, wherein the nanoparticles have a mean size of less than about 200 nm.

Page 9 of 14

pa-1046029 v4



Application No. 10/731,224 (LVM 225602)

Reply to Office Action

150. (New) The pharmaceutical composition of claim 120, wherein the nanoparticles have a mean size of less than about 200 nm.

151. (New) The pharmaceutical composition of claim 126, wherein the nanoparticles have a mean size of less than about 200 nm.

152. (New) The pharmaceutical composition of claim 131, wherein the nanoparticles have a mean size of less than about 200 nm.

153. (New) The pharmaceutical composition of claim 140, wherein the nanoparticles have a mean size of less than about 200 nm.

154. (New) The pharmaceutical composition of claim 145, wherein the nanoparticles have a mean size of less than about 200 nm.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☒ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**